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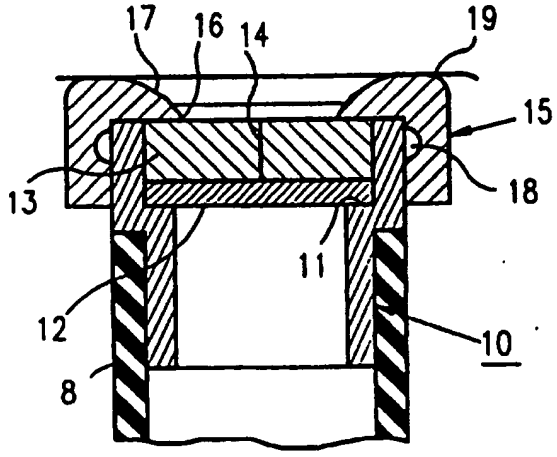
(54) Title: INFUSION BAG WITH INJECTION PORT

(57) Abstract

This invention is an infusion bag having an injection port (10) for injecting a substance into an infusion liquid in the infusion bag, characterized in that the injection port is closed by an elastomeric plug (13) which is preformed with a slit (14) for receiving a blunt cannula therethrough to inject said substance into the infusion bag, and which reseals itself after the blunt cannula has been removed, and in that the injection port further includes a separator layer (12) on the inner face of the elastomeric plug, the separator layer being made of a material and of a thickness to be pierceable by a blunt cannula, but when not pierced, to prevent the infusion liquid from reaching and penetrating the slit during autoclaving of the infusion bag to sterilize the infusion liquid therein.



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INFUSION BAG WITH INJECTION PORT

The present invention relates to infusion bags for administering infusion liquids to subjects, and particularly to an infusion bag including a novel injection port construction for injecting a substance into the infusion bag.

Infusion bags filled with an infusion liquid, such as saline water, have to be sterilized and maintained in a sterile condition for a long period of time, in the order of two years. Blunt cannulas are now coming into increasing use in place of hypodermic needles in order to reduce the danger of infection by accidental contact with a contaminated needle. In blunt cannula constructions, the device to be penetrated is closed by an elastomeric plug which is preformed with a slit to accommodate the blunt cannula, but which reseals itself after the blunt cannula has been removed. If such a construction is used in infusion bags, which are sterilized by autoclaving at a high temperature, there is a danger that the high temperature steam produced will deleteriously affect the elastomeric plug, and particularly the slit formation therein, such that the infusion liquid in the bag will not be able to maintain its sterility condition for the required long shelf life.

An object of the present invention is to provide a novel infusion bag having advantages in the above respects.

According to the present invention, there is provided an infusion bag having an injection port for injecting a substance into an infusion liquid in the infusion bag, characterized in that: said injection port is closed by an elastomeric plug which is preformed with a slit for receiving a blunt cannula therethrough to inject said substance into said infusion bag, and which reseals itself after the blunt cannula has been removed; and in that said injection port further includes a separator layer on the inner face of the elastomeric plug, the separator layer being made of a material and of a thickness to be pierceable by a blunt cannula, but when not pierced, to prevent the infusion liquid from reaching and penetrating the slit during autoclaving of the infusion bag to sterilize the infusion liquid therein.

The separator layer is preferably of polyethylene, polyvinyl chloride, nylon or polypropylene; and is preferably of a thickness of 0.05 to 0.30 mm.

According to further features in the preferred embodiments of the invention described below, the injection port is of a tubular configuration joined at its inner end to the infusion

bag and formed at its outer end with an internal annular shoulder receiving the separator layer and the elastomeric plug thereover.

In one described embodiment, the injection port further includes a cap applied over the outer end of the infusion port to retain the elastomeric plug and separator layer. The cap is formed with a central opening aligned with the slit to permit a blunt cannula to be inserted into the plug via the slit for injecting a substance into the infusion bag. In the described preferred embodiment, the central opening in the cap is bordered by inwardly tapering sides of the cap to guide the blunt cannula to the slit.

In a second described embodiment, the outer end of the injection port is integrally formed with an inturned annular rim engaging the peripheral outer face of the elastomeric plug for retaining the plug and the separator layer.

According to an additional feature in the preferred embodiments of the invention described below, the infusion bag further includes a removable, tamper-proof foil applied over the outer face of the plug.

As will be more particularly described below, an infusion bag constructed with the separator layer prevents the infusion liquid within the bag from reaching the elastomeric plug, and particularly from penetrating the slit, when the infusion bag is autoclaved to sterilize the infusion liquid. Such a construction thereby maintains the sterility of the infusion liquid, and the integrity of the elastomeric plug and slit, for the long shelf life required for such infusion bags.

Further features and advantages of the invention will be apparent from the description below.

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 illustrates one form of infusion bag constructed in accordance with the present invention;

Fig. 2 is an enlarged sectional view illustrating the construction of the injection port in the infusion bag of Fig. 1; and

Fig. 3 is an enlarged sectional view illustrating another construction of the injection port which may be used in the infusion bag of Fig. 1.

The infusion bag illustrated in Fig. 1, and therein generally designated 2, is made of a pliable, transparent plastic material for receiving an infusion liquid, such as saline water. The bag is formed at one end with an opening 4 for suspending the bag at the time of

administering the infusion liquid to a subject. The opposite end of the bag includes a tube defining an infusion port 6 for connection to an infusion tubing assembly through which the infusion liquid within the bag is administered to the subject. The infusion bag 2 further includes another tube 8 defining an injection port, generally designated 10, for injecting a substance into the infusion liquid within the bag, if so desired, before the infusion liquid is administered to the subject.

In the conventional infusion bag constructions, the injection port 10, sometimes called the injection site, is closed by an elastomeric plug or membrane pierced by a hypodermic needle at the time of injecting the substance into the bag. In the construction illustrated in the drawings, the injection port 10 is closed by a pre-slitted elastomeric plug for receiving a blunt cannula to inject the substance into the infusion bag, to thereby reduce the danger of accidental infection by inadvertent contact with a contaminated hypodermic needle. However, when a pre-slitted elastomeric plug is used, there is a danger that the slit in the elastomeric plug, particularly if the infusion bag is sterilized by high-temperature autoclaving, will not maintain its integrity, and thereby the sterility of the infusion liquid within the bag, for the long shelf life (usually at least two years) required for such sterilized infusion bags.

Figs. 2 and 3 illustrate two constructions of the injection port 10 to solve this problem.

The injection port 10 illustrated in Fig. 2 is applied to the outer end of tube 8 joined at its inner end to the infusion bag. Injection port 10 is formed at its outer end with an internal annular shoulder 11. Received on annular shoulder 11 are a separator layer 12, and thereover an elastomeric plug 13, such as of a rubber latex. Plug 13 is preformed with a slit 14 for receiving a blunt cannula (not shown) used to inject a substance into the infusion bag prior to administering the infusion liquid. Slit 14 may extend only partly through plug 13. e.g., terminating just short of its lower face, such that the slitted and unslitted parts are penetrated by the blunt cannula when inserted into the plug. Preferably, however, slit 14 is formed completely through plug 13 to facilitate the insertion of the blunt cannula through the plug.

The elastomeric plug 13, and the underlying separator layer 12, are retained firmly against shoulder 11 of the injection port 10 by a cap 15 applied over the outer end of the injection port 10. Cap 15 is formed with a central opening 16 to permit a blunt cannula (not shown) to be inserted into and through plug 13 via its slit 14 for injecting a substance into the solution bag before the solution therein is administered to the subject. Opening 16 in the cap is bordered by inwardly tapering sides 17 of the cap to guide the blunt cannula to the slit 14. An annular seal 18 is provided between the inner surface of cap 15 and the outer surface of

the outer end of the injection port 10. A removable tamper-proof foil 19 is applied over the outer face of cap 15.

Separator 12 is made of a material and of a thickness which prevent the infusion liquid from reaching and penetrating the preformed slit 14 when the infusion bag is autoclaved at a high temperature (e.g., about 130 C) to sterilize the infusion liquid, but which enable the separator to be easily pierced by a blunt cannula if and when a substance is to be injected into the bag via the injection port. A particularly suitable material for this purpose is polyethylene of a thickness of 0.15 mm. Other materials that may be used are polyvinyl chloride, nylon and polypropylene. Generally, it is preferred to have this separator of a thickness of 0.05 to 0.30 mm.

The separator layer 12 thus isolates the elastomeric plug 13 from the contents of the infusion bag, and therefore permits the infusion bag to be sterilized by autoclaving without danger that the steam produced during the process will reach the elastomeric plug, its preformed slit 14, or the infusion liquid within the bag. The separator layer therefore also maintains the integrity of the elastomeric plug and the slit for a long period of time after sterilization, and thereby maintains the sterile condition of the contents of the infusion bag, for the long shelf life, usually about two years, required for such infusion bags. The tamper-proof foil 19 further protects the plug and the contents of the infusion bag.

Fig. 3 illustrates an alternative construction that may be used for the injection port, therein generally designated 20. The infusion port in Fig. 3 is also formed at its outer end with an internal annular shoulder 21 for receiving thereon the separator 22 and also the elastomeric plug 23, the latter being preformed with a slit 24 as described above with respect to Fig. 2. In this case, however, the separator layer and elastomeric plug are retained by an inturned annular rim 25 integrally formed at the outer end of the tubular injection port 20 and engaging the outer peripheral face of the elastomeric plug 23. Such a rim, therefore, also defines a central opening 26 aligned with the slit 24 to enable the blunt cannula to be inserted into the slit 24 for injecting a substance into the infusion bag. As in Fig. 2, a removable, tamper-proof foil 29, is applied over the outer face of the retainer rim 25 of the elastomeric plug 23.

The construction illustrated in Fig. 3 is otherwise the same, and provides the same advantages, as described above with respect to Fig. 2.

While the invention has been described with respect to two preferred embodiments, it will be appreciated that these are set forth merely for purposes of example, and that many other variations, modifications and applications of the invention may be made.

CLAIMS

1. An infusion bag having an injection port for injecting a substance into an infusion liquid in the infusion bag, characterized in that:

said injection port is closed by an elastomeric plug which is preformed with a slit for receiving a blunt cannula therethrough to inject said substance into said infusion bag, and which reseals itself after the blunt cannula has been removed;

and in that said injection port further includes a separator layer on the inner face of said elastomeric plug, said separator layer being made of a material and of a thickness to be pierceable by a blunt cannula, but when not pierced, to prevent the infusion liquid from reaching and penetrating the slit during autoclaving of the infusion bag to sterilize the infusion liquid therein.

2. The infusion bag according to Claim 1, wherein said separator layer is of polyethylene, polyvinyl chloride, nylon, or polypropylene.

3. The infusion bag according to either of Claims 1 or 2, wherein said separator layer is of a thickness of 0.05 to 0.30 mm.

4. The infusion bag according to any one of Claims 1-3, wherein said injection port is of tubular configuration joined at its inner end to said infusion bag and formed at its outer end with an internal annular shoulder receiving said separator layer and said elastomeric plug thereover.

5. The infusion bag according to any one of Claims 1-4, wherein said elastomeric plug is made of a rubber latex.

6. The infusion bag according to Claim 5, wherein said injection port further includes a cap applied over the outer end of the infusion port to retain said elastomeric plug and separator layer; said cap being formed with a central opening aligned with said slit to permit a blunt cannula to be inserted into the plug via said slit for injecting a substance into the infusion bag.

7. The infusion bag according to Claim 6, wherein said central opening in said cap is bordered by inwardly tapering sides of the cap to guide the blunt cannula to said slit.

8. The infusion bag according to Claim 5, wherein the outer end of said injection port is integrally formed with an inturned annular rim engaging the peripheral outer face of the elastomeric plug for retaining said plug and said separator layer.

9. The infusion bag according to any one of Claims 1-8, wherein the infusion bag further includes a removable, tamper-proof foil applied over the outer face of the plug.

10. The infusion bag according to any one of Claims 1-9, wherein the infusion bag further includes an infusion port for connecting an infusion tubing assembly thereto.

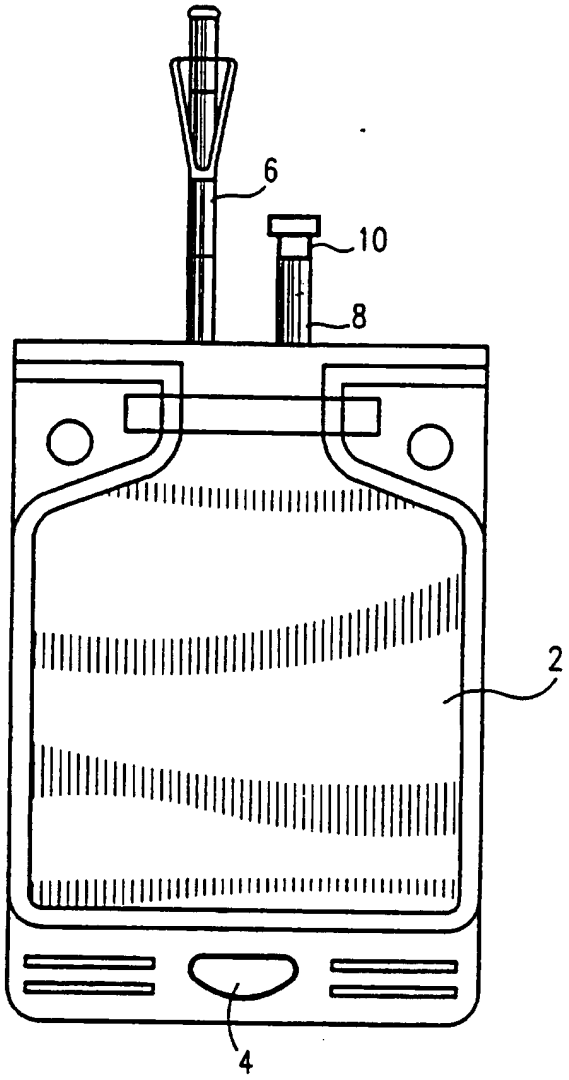

FIG. 1

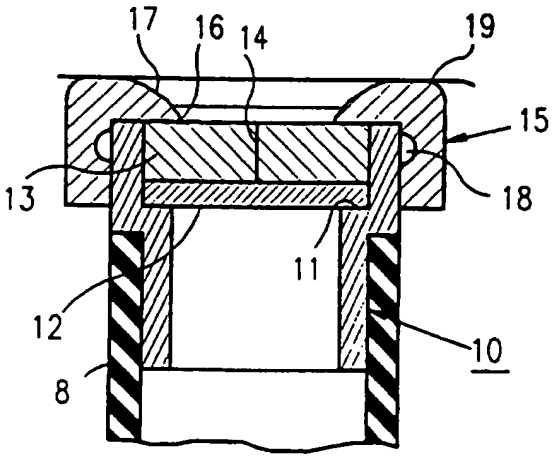

FIG. 2

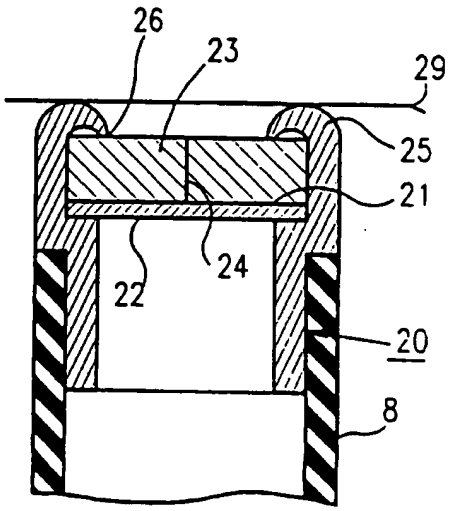

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/02580

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 19/00
US CL :604/415

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/205, 206, 262, 403, 408, 411, 412, 415;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,211,638 (DUDAR ET AL.) 18 May 1993, see Figs. 6-13.	1-10
Y	US, A, 5,188,628 (RANI ET AL.) 23 February 1993, see separator layer (27).	1-10
A	US, A, 4,592,092 (MCPHEE) 27 May 1986, in regards to claim 9 see Fig. 2 element (21).	1-10
A	US, A, 4,596,573 (DONNAN ET AL.) 24 June 1986, see all figures.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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